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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,093	03/12/2001	Robert Scott	6511-C1-11-EJF	7994

29668 7590 06/09/2003

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EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	14

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,093	SCOTT ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003 (paper no.12)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,41,54-57 and 60-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,41,54-56 and 60-62* is/are rejected.

7)☒ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the Statement filed 10/17/02, the Petition under 37 CFR 1.137(b) and the Amendment, both filed 04/01/03 is acknowledged.

Claims 34, 41, 54-57 and 60-62 are pending. Claim 34 has been amended. Claims 34, 41, 54-56 and 60-62 are rejected. Claim 57 is objected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34, 41 and 54-56 are rejected und r 35 U.S.C. 103(a) as being unpatentable over Hansen *et al.* (US Pat. No. 6, 423,346 B1).

Hansen et al. teach a fish gelatinous composition containing at least 50% (and more preferably at least 70% and at least 90%) by weight of fish gelatin, water (0-10%) and a hydrocolloid system comprising various polysaccharides such as gum arabic, tragacanth gum, karaya gum, ghatti gum, agar gum, alginates, guar gum, carrageenan, starches and celluloses (see reference column 2); (col. 3, lines 43-67); (col. 5) and examples.

Hansen et al. while teaching a fish gelatinous composition containing at least 50% by weight of fish gelatin, 0-10% water and a hydrocolloid system, do not explicitly teach the specifically claimed amount of the hydrocolloids. It would have been obvious to one of ordinary skill in the art at the time the invention was made that suitable amounts of a hydrocolloid could be determined through routine or manipulative experimentation. The expected result would be a fish gelatinous composition wherein the hydrocolloid would function as a protective agent aid in increasing the mechanical strength, improve storage stability, reduce degradation of the active ingredient and act as an emulsifier.

Hansen et al. teach a fish gelatinous composition in the form of a tablet or microcapsule. Hansen et al. do not teach a gelatinous composition in the form of a capsule, wherein the capsule is made by dipping a forming mold into a gelatinous solution.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpat ntable over Jones (US Pat. No. 4, 892,766).

Jones teaches two-piece hard gelatin capsules comprising water (about 13%-16%) and polysaccharides in an amount up to about 10%, wherein the capsules can be made by dipping mould pins into a hot solution of gelatin (or by incorporating the fibrous materials into an aqueous suspension of molten gelatin), removing the pins from the gelatin solution, allowing the gelatin to set by drying and stripping the shells from the pins (see reference columns 1 and 2).

Therefore, it would have been obvious to one of ordinary skill in the pharmaceutical art at the time the invention was made to formulate a two-piece hard gelatin capsule made by dipping a capsule into a forming mold with an aqueous gelatin solution because it could help overcome problems of embrittlement and splitting of the capsule walls after storage. The expected result would be an improved hard gelatin capsule resistant to embrittlement, cracked or split capsules and thus enhanced storage capabilities.

Response to Arguments

Applicant's arguments filed 04/01/03 have been fully considered but they are not persuasive.

Firstly, the applicant argued regarding Hansen et al (US '346), stating, "All of the examples fail to mention the use of a hydrocolloid in the preparation of the microcapsules."

This argument has been fully considered, but was not found to be persuasive. Hansen teaches gelatin microcapsules containing fish gelatin, water, hydrocolloids and physiologically active ingredients. The teachings of the reference are not limited to the examples of what the reference fairly suggests to one of ordinary skill in the art.

Secondly, the applicant argued, "There is no teaching or suggestion of how to make a fish gelatin composition which is suitable for making hard gelatin capsules and which has gelling properties similar to gelatin compositions which do not contain fish gelatin."

This argument has been fully considered, but was not found to be persuasive. It is the examiner's position that one of ordinary skill in the art would find any gelatin as being suitable for use in the method of making the gelatin capsules. It is also considered obvious to form gelatin capsules by including any gelatin with water, hydrocolloids and active ingredients, as is taught by the prior art. Furthermore, the future intended use to make hard gelatin capsules does not impart patentability to the composition that has been suggested by the prior art.

Thirdly, the applicant argued, "Hansen does not even require the presence of water (0-10% by weight)."

This argument has been fully considered, but was not found to be persuasive. As admitted by the applicant, the prior art teaches up to 10% by weight of water, which is clearly within the applicant's claimed range of 7-17% by weight of water.

Next, the applicant argued regarding Jones (US '766), stating, "Jones does not mention fish gelatin anywhere in the text of the patent. Jones is directed to a hard gelatin capsule manufacturing process, but doesn't recognize the problems of using fish gelatin to achieve such hard gelatin capsules nor does Jones provide a solution to the problem."

This argument has been fully considered, but was not found to be persuasive. Jones was relied upon for the teaching of hard gelatin capsules made by dipping mould pins into a hot solution of gelatin and not for the specific teaching of fish gelatin, as Hansen had initially taught the incorporation of fish gelatin in microcapsules. Furthermore, the future intended use to make hard gelatin capsules does not impart patentability to the composition that has been suggested by the prior art.

Regarding claim 54, the generic language of "container" reads on the tablet of Hansen, who teaches a fish gelatinous composition comprising fish gelatin, water, hydrocolloids and pharmaceutical active substances.

Finally, it is noted that the examiner is using the term "capsule" and "microcapsule" interchangeably and the specification fails to impart any distinction by the presentation of the descriptions related to size.

Allowable Subject Matter

Claim 57 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
June 04, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600